Confidential

***IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION*-MDL No. 2804**

SCOTT L. WEXELBLATT, MD EXPERT REPORT

MARCH 25, 2019

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I. BACKGROUND AND QUALIFICATIONS

1. My name is Scott L. Wexelblatt, MD. I am the Regional Medical Director of Newborn Services at Cincinnati Children's Hospital Medical Center and an Associate Professor in the Department of Pediatrics, University of Cincinnati College of Medicine.

2. I have been asked to provide an expert opinion on the effects of opioid addiction on pregnant mothers and infants with a focus on neonatal abstinence syndrome (NAS) and its impact on Cuyahoga and Summit Counties (collectively, "the Counties").

3. I am a pediatrician and researcher focused on improving perinatal health outcomes in regional populations. I am currently the Regional Director of Newborn Services for Cincinnati Children's Hospital Medical Center (CCHMC) Perinatal Institute, which serves eight level 2 hospitals and three level 1 nurseries in our region.

4. I am a faculty member of Ohio Perinatal Quality Collaborative (OPQC) on the Neonatal Abstinence Syndrome project. OPQC is a statewide consortium of perinatal clinicians, hospitals, policymakers and governmental entities that aims, through the use of improvement science, to reduce preterm births and to improve perinatal and birth outcomes in Ohio. OPQC has been working in collaboration with the Ohio Department of Mental Health and Addiction Services (ODHMAS), the Ohio Department of Medicaid (ODM), and the Ohio Department of Health (ODH) to improve outcomes for pregnant women with opioid use disorder and their infants.

5. As the regional faculty representative for the Ohio Children's Hospital Association (OCHA) subcommittee on neonatal abstinence syndrome, I helped establish a protocol for NAS for twenty Ohio children's and maternity hospitals.[1] I led the data analysis and was a co-first author on a publication of key findings from OCHA. OCHA's findings showed improved outcomes following an infant's in utero exposure to opioids through the utilization of standard treatment protocols with stringent weaning guidelines.[2]

6. Based on our primary findings, I helped establish a standardized protocol for NAS, and spread this new protocol to hospitals to implement. I was the co-author and led the data analysis on our publication showing marked improvement with implementation of this protocol.[3]

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[1] Hall ES, Wexelblatt SL, Crowley M, et al. A Multicenter Cohort Study of Treatments and Hospital Outcomes in Neonatal Abstinence Syndrome. *Pediatrics*. 2014;134(2):e527-534. Six hospitals' neonatology groups covered newborn nurseries in twenty hospitals. The six hospitals included Rainbow Babies and Children's Hospital (Cleveland); Akron Children's Hospital; Cincinnati Children's Hospital; Dayton Children's Hospital; Nationwide Children's Hospital (Columbus); ProMedical Toledo Children's Hospital.

[2] *Ibid*.

[3] Hall ES, Wexelblatt SL, Crowley M, et al. Implementation of a Neonatal Abstinence Syndrome Weaning Protocol: A Multicenter Cohort Study. *Pediatrics*. 2015;136(4):e803-810.

7. Building upon my work with the OCHA collaborative, I served as a primary or co-investigator in several additional regional analyses designed to provide evidence for further optimizing NAS guidelines.[4] Analyses of outcomes following methadone versus buprenorphine weaning and a comparative effectiveness evaluation of conventional methadone weaning versus weaning with a pharmacokinetic modeled methadone protocol were published.[5,6]

8. Through my role as a faculty member of the OPQC, I am currently participating in disseminating the OPCQ's findings to 52 delivery hospitals in Ohio to improve the care of the opioid-exposed infant. Through our statewide collaborations of OCHA and OPQC, we have created a standardized protocol to safely decrease the length of hospital stay.[7]

9. In my role as Regional Director of Newborn Care, I led the implementation of universal maternal testing in 18 hospitals in Southwest Ohio after demonstrating in a pilot study that universal testing was superior to the risk-based screen which was being utilized at that time. This has led to earlier identification and diagnosis of opioid exposed neonates, leading to improved hospital care, and an improved discharge care plan and follow up.[8]

10. I received a B.A. *cum laude* from the University of Delaware (Psychology) in 1992 and an M.D. from University of Vermont College of Medicine in 1996. I completed postgraduate training, pediatric residency and internship at the Cincinnati Children's Hospital Medical Center (1996-1999).

11. I am licensed to practice medicine in the State of Ohio and Board Certified by the American Board of Pediatrics (1999 with recertifications in 2007 and 2015).

12. My curriculum vitae, a copy of which is attached as **Exhibit A**, further describes my education, background, and qualifications. In addition, it lists those matters in which I have testified as an expert at trial or deposition within the past four years.

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[4] Walsh MC, Crowley M, Wexelblatt S, et al. Ohio Perinatal Quality Collaborative Improves Care of Neonatal Narcotic Abstinence Syndrome. *Pediatrics*. 2018;141(4).

[5] Hall ES, Rice WR, Folger AT, Wexelblatt SL. Comparison of Neonatal Abstinence Syndrome Treatment with Sublingual Buprenorphine versus Conventional Opioids. *American Journal of Perinatology*. 2018;35(4):405-412.

[6] Hall ES, Isemann BT, Wexelblatt SL, et al. A Cohort Comparison of Buprenorphine versus Methadone Treatment for Neonatal Abstinence Syndrome. *The Journal of Pediatrics*. 2016;170:39-44 e31.

[7] Hall, *Pediatrics* (2015)

[8] Wexelblatt SL, Ward LP Torok K, Tisdale E. Meinzen-Derr JK, Greenberg JM, Universal Maternal Drug Testing in a High-Prevalence Region of Prescription Opiate Abuse. *The Journal of Pediatrics*, 2015, 166 (3); 582-586.

13. I have authored or coauthored numerous publications, the title and citations of which are also listed on **Exhibit A**. This list includes publications I have authored or co-authored in the last ten years.

14. I am being compensated at a rate of $650 per hour for my services in this litigation. I am also being reimbursed for all reasonable expenses incurred for my work on this litigation. No part of my compensation is contingent upon the outcome of this litigation, and I have no interest in the litigation or with either party.

II. BRIEF SUMMARY OF OPINIONS

15. Based upon my qualifications, experiences and research, as well as the information referenced in this report, I plan to offer the opinions set forth below. This report draws upon my professional experiences, research and participation in studies as outlined in my qualifications relating to opioid exposed infants, a literature search of scientific publications and publications from authoritative sources such as the Center for Disease Control (CDC), the Substance Abuse and Mental Health Services Administration (SAMSHA), the American College of Obstetricians and Gynecologists (ACOG), World Health Organization (WHO), Ohio Department of Mental Health and Addiction Services (ODHMAS), Ohio Department of Health (ODH), Ohio Department of Medicaid (ODM), and the Ohio Perinatal Quality Collaborative (OPQC).

    a. The use and exposure of opioids among pregnant women continues to grow throughout the United States.

    b. Neonatal abstinence syndrome (NAS) is a clinical diagnosis given to infants who experience withdrawal signs and symptoms after in utero exposure to opioids.

    c. Withdrawal signs develop in 55% to 94% of opioid exposed infants, with 30-65% of those infants requiring pharmacologic treatment for severe withdrawal.

    d. The increasing number of women with opioid use disorder in Cuyahoga and Summit Counties and the growing incidence of NAS, is a significant public health issue. The Counties will need to build upon existing programs and develop new multidisciplinary programs to improve the outcomes of women with opioid use disorder, mothers, and infants. As the rate of infants born with NAS continues to climb, additional and enhanced services are needed in Cuyahoga and Summit Counties, including programs focused on prevention, treatment, and early intervention.

    e. Preventing opioid exposure among women of childbearing age and pregnant women will greatly reduce the number of babies with narcotic exposure and reduce the need for treatment of NAS.

    f. Effective prevention programs will need to educate women of childbearing age about substance abuse prevention and raise awareness of the effects of opioid use

prior to and during pregnancy, and provide counseling for women being treated for opioid use disorder.

g. Emergency rooms, health clinics, community drug treatment centers, and other service providers should expand screening programs in order to identify women in need of intervention and treatment referral.

h. Any programs geared towards prevention and/or treatment must recognize barriers to treatment for women during pregnancy, delivery and postpartum.

i. Standardized NAS assessment and treatment protocols improve outcomes for care for opioid-exposed infants in Ohio.

j. Universal maternal screening prenatally and testing at the time of delivery improves the identification of infants at risk for the development of NAS.

k. Pharmacological support with opioids has been shown to be the best treatment when medication is needed for withdrawal for babies with NAS.

l. Existing medication assisted treatment (MAT) programs should be expanded, along with coordinated supportive services that mitigate barriers women may experience in accessing these treatment.

m. Access to buprenorphine replacement therapy, which can decrease the severity of newborn withdrawal, should be expanded.

n. Continued study on long terms outcomes and personalized pharmacological treatment are important for the optimization of outcomes for opioid-affected babies.

o. The effective long-term care of children and families impacted by opioids will require programs that provide: family-centered care, such as residential care for pregnant and postpartum women with opioid use disorder; comprehensive pediatric care, such as regular preventative care for children; and developmental follow-up programs for children, which may include regular developmental screening, occupational therapy, and physical therapy.

p. It is my opinion that an optimal maternal care program would allow women with opioid use disorders to be identified during pregnancy and subsequently provided with prenatal care and other supportive services. The program would provide for the development of an individualized treatment care plan for both mother and baby, as well as a discharge plan with home visitation, early intervention services, and referrals to other supportive services. Care would be coordinated through an interdisciplinary team that may include specialists in perinatology, neonataology, addiction medicine, psychiatry, social work, case management, and nutrition. Referrals to the program would come from throughout the community, including emergency departments, obstetric triage, women's health centers, family medicine

providers, addiction medicine providers, community drug treatment centers, and hospitals.

III. BASIS FOR OPINIONS

A. Opioid Use in the United States and Ohio

16. The use of opioids has escalated throughout the United States resulting in an epidemic of opioid misuse, overdose, and death. As a consequence, there are more than 131 opioid overdose deaths in the United States each day.[9]

17. As of 2017, overdose deaths involving prescription opioids were five times higher than they were in 1999.[10] In addition to overdose deaths, the Center for Disease Control and Prevention (CDC) reports that "nonfatal overdoses from both prescription and illicit drugs are responsible for increasing emergency department visits and hospital admissions."[11]

18. Ohio has been recognized as among the top five states with the highest rates of opioid related overdose deaths.[12] According to the Ohio Department of Health, "from 2000 to 2017, Ohio's death rate due to unintentional drug poisonings increased 1,081 percent, and the increase in deaths has been driven largely by opioid-related overdoses."[13] In 2016, Ohio had a rate of 32.9 opioid-related overdose deaths per 100,000 persons – more than double the national average.[14]

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[9] U.S. Department of Health and Human Services (HHS), Office of the Surgeon General, *Facing Addiction in America: The Surgeon General's Spotlight on Opioids*. Washington, DC: HHS, September 2018.

[10] Centers for Disease Control and Prevention (CDC). 2018 Annual Surveillance Report of Drug-Related Risks and Outcomes — United States. Surveillance Special Report. Centers for Disease Control and Prevention, U.S. Department of Health and Human Services. Published August 31, 2018. Available at https://www.cdc.gov/drugoverdose/pdf/pubs/2018- cdc-drug-surveillance-report.pdf.

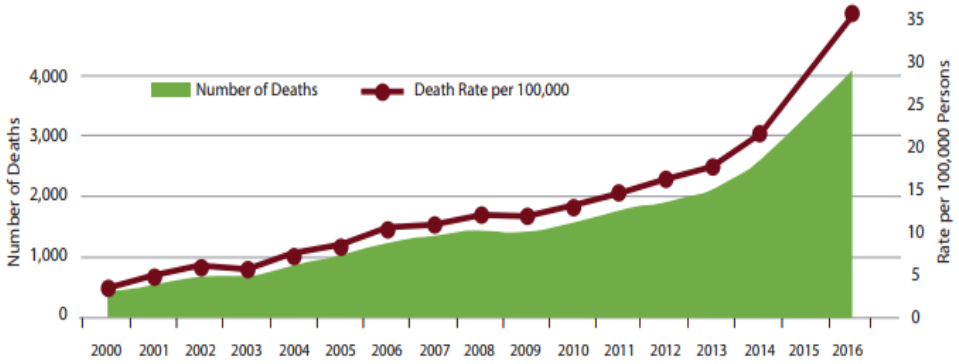
[11] *Ibid*.

[12] National Institute on Drug Abuse (NIDA), *Opioid-Related Overdose Deaths: Ohio*, February 2018. Available at https://www.drugabuse.gov/drugs-abuse/opioids/opioid-summaries-by-state/ohio-opioid-summary.

[13] Ohio Department of Health, *Drug Overdose*, July 2, 2018. Available at https://odh.ohio.gov/wps/portal/gov/odh/know-our-programs/violence-injury-prevention-program/Drug-overdose/.

[14] NIDA 2018

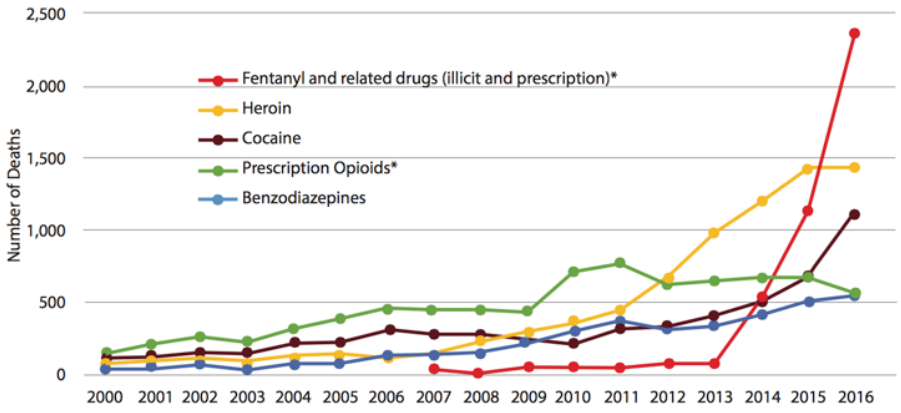
Figure 8. Number of Deaths and Annual Age-Adjusted Death Rate* per 100,000 Population from Unintentional Drug Overdose by Year, Ohio Residents, 2000-2016



Source: Ohio Department of Health, Bureau of Vital Statistics; analysis conducted by ODH Violence and Injury Prevention Program.
*The death rate is presented as age-adjusted which allows a comparison of death rates between populations (e.g. counties and states). The rates are adjusted to the U.S. 2000 standard population to allow a comparison of the overall risk of dying between different populations.

Unintentional Overdoses Involving Select Drugs and Age-Adjusted Death Rate

Figure 7. Number of Unintentional Drug Overdose Deaths Involving Selected Drugs, by Year, Ohio, 2000-2016



Source: Ohio Department of Health, Bureau of Vital Statistics; analysis conducted by ODH Violence and Injury Prevention Program.
Multiple drugs are usually involved in overdose deaths. Individual deaths may be reported in more than one category.
Includes Ohio residents who died due to unintentional drug poisoning (underlying cause of death ICD-10 codes X40-X44).
* Excludes deaths involving fentanyl and related drugs.

B. Rates of Opioid Exposure Among Women in the US and Ohio

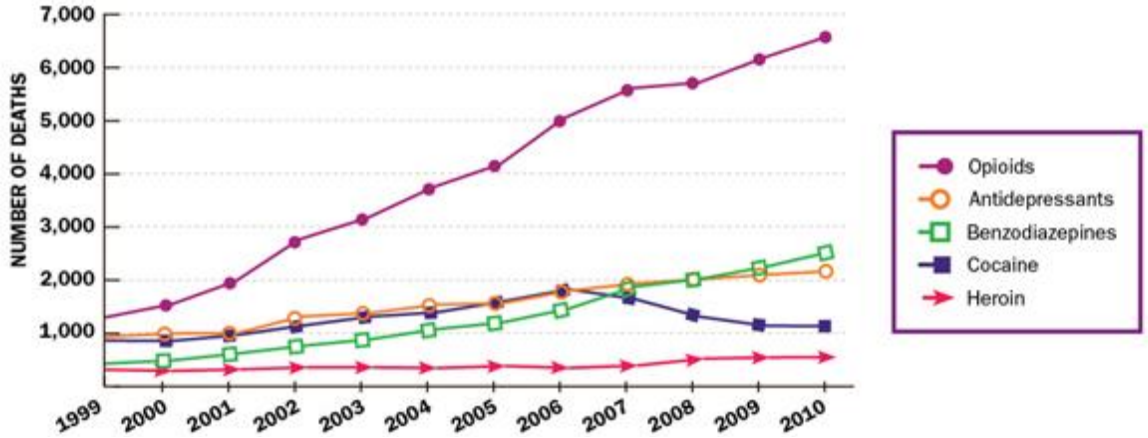
19. Opioid use among women has increased dramatically.[15]

[15] American Society of Addiction Medicine (ASAM), *Opioid Addiction, 2016 Facts and Figures*. Available at https://www.asam.org/docs/default-source/advocacy/opioid-addiction-disease-facts-figures.pdf.

20. In 2013, the CDC highlighted the growing epidemic of prescription opioid overdoses among women, finding:

- About 18 women die every day of a prescription painkiller overdose in the U.S., more than 6,600 deaths in 2010;
- Prescription painkiller overdoses are an under-recognized and growing problem for women;
- Between 1999 and 2010, overdose deaths from prescription painkillers increased more than 400% among women, compared to an increase of 237% among men;
- Between 2002 and 2013, heroin use among women increased 100% compared to an increase of 50% among men;
- Nearly 48,000 women died of prescription painkiller overdoses between 1999 and 2010;
- For every one woman who dies of a prescription painkiller, thirty go to the emergency room for painkiller misuse or abuse.
- Every three minutes, a woman goes to the emergency department for prescription painkiller misuse or abuse;
- Women between the ages of 25 and 54 are most likely to go to the emergency department because of prescription painkiller misuse or abuse.[16]

Prescription painkiller overdose deaths are a growing problem among women.



[16] CDC, *Vital Signs* (2013)

SOURCE: National Vital Statistics System, 1999-2010 (deaths include suicides)

Drug overdose deaths among women, by select drug class, United States, 2004-2010. Data from National Vital Statistics System

21. Between 2000 and 2009, maternal antepartum opioid use increased from 1.19 to 5.63 per 1000 hospital births annually.[17] Between 2005 and 2011, more than 14% of pregnant women were legally dispensed an opioid at some time during pregnancy.[18]

22. By 2011, more than 1% of pregnant women used opioid-based pain relievers or heroin illicitly.[19] By 2012, 27.7% of privately insured and 39.4% of Medicaid insured-women of reproductive age filled prescriptions for opioid medications.[20]

23. According to the CDC, women are more likely to experience chronic pain and use prescription opioid pain medications for longer periods and in higher doses than men.[21] Studies have also shown that women who use opioids progress to dependence more quickly than men and experience more cravings than men;[22] that psychological and emotional distress are identified as risk factors for hazardous opioid prescription use among women but not men;[23] and that women who are caregivers may face additional barriers to treatment for substance abuse disorder such as lack of childcare.[24]

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[17] Patrick SW, Schumacher RE, Benneyworth BD, Krans EE, McAllister JM, Davis MM. Neonatal Abstinence Syndrome and Associated Health Care Expenditures: United States, 2000-2009. *JAMA : the Journal of the American Medical Association*. 2012;307(18):1934-1940.

[18] Bateman, BT, et al, Patterns of Opioid Utilization in Pregnancy in a Large Cohort of Commercial Insurance Beneficiaries in the United States. *Anesthesiology*. 2014:120(5): 1216-1224

[19] Hall, *Pediatrics* (2016).

[20] Ailes EC, Dawson AD, Lind JN, Gilboa SM, Frey MT, Broussard CS, and Honein MA. CDC. Opioid Prescritption Claims Among Women of Reproductive Age – United States, 2008-2012. MMWR. 2015 Jan 23:64(2):37-41.

[21]Centers for Disease Control and Prevention. Prescription Painkiller Overdoses. *Vital Signs*. July 2013. Available at http://www.cdc.gov/vitalsigns/prescriptionpainkilleroverdoses/index.html.

[22] Back SE, Payne RL, Wahlquist AH, et al. Comparative Profiles of Men and Women with Opioid Dependence: Results from a National Multisite Effectiveness Trial. *The American Journal of Drug and Alcohol Abuse*. 2011;37(5):313-323.

[23] Back, SE, Lawson, K, Singleton, L, and Brady, KT. Characteristics and Correlates of Men and Women with Prescription Opioid Dependence. *Addict Behav*. 2011; August; 36(8): 829-834.

[24] Center for Substance Abuse Treatment. Substance Abuse Treatment: Addressing the Specific Needs of Women: Treatment Improvement Protocol (TIP) series 51; vol HHS publication no. (SMA) 09-4426. Rockville, MD: Substance Abuse and Mental Health Services Administration; 2009

24. Unintended pregnancy rates among women with substance abuse disorders are approximately 80 percent, considerably higher than the rate of unintended pregnancies in the general population.[25] According to guidance issued by the Substance Abuse and Mental Health Services Administration (SAMSHA) concerning the treatment of pregnant and parenting women with opioid use disorder, "preventing unintended pregnancies and planning for future pregnancies is critical." [26] SAMSHA recommends that healthcare professions should offer women with opioid use disorder "non-coercive contraception counseling" for prior to leaving the hospital.[27]

25. Opioid use during pregnancy has increased dramatically in recent years as a growing number of women of childbearing age suffer from opioid use disorder.[28] In Ohio, over 4,200 pregnant women were admitted to treatment between 2004 and 2011.[29]

26. Increases in opioid use among pregnant women includes increases in the use of prescription opioids, medication assisted treatment, increases in illicit drug use.[30] Studies have shown substance use during pregnancy to be a ubiquitous problem affecting women across racial, socioeconomic status, and age categories.[31]

27. The increase in utilization of opioids by women of reproductive age and pregnant women is particularly concerning because of the potential effects both on the women and their unborn children.

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[25] The American College of Obstetricians and Gynecologists. ACOG Committee Opinion, Number 711. Opioid use and opioid use disorder in pregnancy. Available at https://www.acog.org/Resources-And-Publications/Committee-Opinions/Committee-on-Obstetric-Practice/Opioid-Use-and-Opioid-Use-Disorder-in-Pregnancy. Published August 2017.

[26] Substance Abuse and Mental Health Services Administration. *Clinical Guidance for Treating Pregnant and Parenting Women with Opioid Use Disorder and Their Infants*. HHS Publication NO. (SMA) 18-5054. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2018.

[27] *Ibid*.

[28] Haight SC, Ko JY, Tong VT, Bohm MK, Callaghan WM. Opioid Use Disorder Documented at Delivery Hospitalization — United States, 1999–2014. *MMWR Morb Mortal Wkly Rep*. 2018;67:845–849. DOI: http://dx.doi.org/10.15585/mmwr.mm6731a1.

[29] Massatti, R., Falb, M., Yors., Potts, L., Beghly, C. & Starr, S., (2013, November) Neonatal abstinence syndrome and drug use among pregnant women in Ohio, 2004-2011. Columbus, OH: Ohio Department of Mental Health and Addiction Services.

[30] Reddy, U. M., Davis, J. M., Ren, Z., & Greene, M. F. (2017). Opioid use in pregnancy, neonatal abstinence syndrome, and childhood outcomes: executive summary of a joint workshop by the Eunice Kennedy Shriver National Institute of Child Health and Human Development, American College of Obstetricians and Gynecologists, American Academy of Pediatrics, Society for Maternal-Fetal Medicine, Centers for Disease Control and Prevention, and the March of Dimes Foundation. *Obstetrics & Gynecology*, 130(1), 10-28.

[31] ACOG Committee Opinion, Number 711 (2017)

28. Opioid use in pregnant women presents risks for the fetus and newborn child. Maternal detoxification can increase the risk of fetal distress and fetal loss.[32] As discussed in greater detail below, untreated opioid use disorder during pregnancy can have devastating consequences for the unborn baby due to the potential for repeated periods of withdrawal.[33] Other risks to the baby include stunted growth, preterm labor, fetal convulsions, and fetal death.[34] Long-term, studies have shown that toddlers and young school age children with prenatal opioid exposure are more likely to have impairments in cognition as well as poorer psychomotor and behavioral outcomes.[35] The mother may also be at increased risk of HIV, HBV, HCV, malnutrition and dangers associated with drug seeking behaviors.[36]

C. Guidelines and Interventions for Pregnant Women with Opioid Use Disorder

29. In 2014, the World Health Organization published guidelines to promote evidence-based advice to health care providers on identifying and managing substance use and substance use disorders in pregnant women. The guidelines strongly recommended that opioid-dependent pregnant women be encouraged to use opioid maintenance treatment (methadone or buprenorphine) whenever available rather than to attempt opioid detoxification. The risk of harm from opioid maintenance treatment is very low as compared to the high risk of relapse to opioid use following detoxification or the "catastrophic" harm to both mother and fetus from failed detoxification. Also strongly recommended was that mothers who are on methadone or buprenorphine maintenance treatment be encouraged to breastfeed unless the risks outweighed the benefits. [37]

30. In 2017, The American College of Obstetricians and Gynecologists' (ACOG), Committee on Health Care for Underserved Women and the American Society of Addiction Medication (ASAM) issued recommendations and conclusions relating to opioid use and opioid use disorder in pregnancy. The Committee Opinion concluded that opioid use in pregnancy has sharply escalated, paralleling the opioid epidemic in the general population and that the use of illicit opioids during pregnancy is associated with an increased risk of

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[32] Hudak ML, Tan RC, Committee On D, Committee On F, Newborn, American Academy of P. Neonatal drug withdrawal. *Pediatrics*. 2012;129(2):e540-560.

[33] National Institute on Drug Abuse (NIDA), Treating Opioid Use Disorder During Pregnancy, National Institutes of Health; U.S. Department of Health and Human Services, July 2017

[34] *Ibid*.

[35] Baldacchino, A., Arbuckle, K., Petrie, D. J., & McCowan, C. (2014). Neurobehavioral consequences of chronic intrauterine opioid exposure in infants and preschool children: a systematic review and meta-analysis. BMC psychiatry, 14, 104. doi:10.1186/1471-244X-14-104.

[36] *Ibid*.

[37] World Health Organization: *Guidelines for Identification and Management of Substance Use and Substance Use Disorders in Pregnancy*. October 2014. Available at http://www.who.int/substance_abuse/publications/pregnancy_guidelines/en/

adverse outcomes. The Committee's opinion is that the current standard of care for pregnant women with opioid dependence is referral for medication-assisted therapy with methadone, but emerging evidence suggests that buprenorphine also should also be considered.[38, 39]

31. Recognizing the urgent need to develop clinical guidelines for professionals who care for pregnant women with OUD and their substance exposed infants, in 2018 SAMSHA published a comprehensive guide identifying effective interventions for pregnant women with OUD and their exposed infants. The guidelines ensure health professionals have access to and aware of up-to-date research addressing opioid use disorders and prenatal exposures. Focused on prenatal, infant and maternal postnatal care, the Guide "recommends feasible, standard approaches to the care of pregnant and parenting women with OUD and their infants that can be adopted in care settings throughout the United States." Recommended practices include prenatal screenings and assessments, use of pharmacotherapy during prenatal and post-natal care, screening and assessment for NAS along with early interventions strategies and developmental assessments for infant care.[40]

32. A recent study published in the American College of Obstetricians and Gynecologists (ACOG) looked at women in Massachusetts with evidence of opioid use disorder who delivered a live born infant between 2012 and 2014. 2.3% (4,154) of deliveries were to women with evidence of opioid use disorder in the year before or after delivery. Two hundred forty-two women experienced an opioid related overdose (231 nonfatal, 11 fatal) in the year before or after delivery. The study found that the year after delivery was an especially vulnerable period for women with evidence of opioid use disorder. Specifically, the highest overdose rates occurred in the period 7-12 months after delivery. Women receiving pharmacotherapy had reduced overdose rates in the early postpartum period. This report demonstrates the need not only for support and intervention for women during pregnancy, but into the first year postpartum to prevent and reduce overdose events.[41]

33. Expanding access to MAT is critical to improving outcomes among pregnant women with opioid use disorders. However, despite the established benefits of MAT programs for this population, women may experience a variety of potential barriers to entering treatment and

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[38] Winhusen T, Wilder C, Wexelblatt SL, Theobald J, Hall ES, Lewis D, et al. Design considerations for point-of-care clinical trials comparing methadone and buprenorphine treatment for opioid dependence in pregnancy and for neonatal abstinence syndrome. *Contemp Clin Trials*. 2014;39:158–65.

[39] ACOG Committee Opinion, Number 711 (2017).

[40] Substance Abuse and Mental Health Services Administration (SAMSHA). *Clinical Guidance for Treating Pregnant and Parenting Women with Opioid Use Disorder and Their Infants*. HHS Publication NO. (SMA) 18-5054. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2018

[41] Schiff D, Nielsen T, Terplan Mishka, Hood M, Bernson D, Diop H, Bharel M, Wilens T, LaRochelle M, Walley A, Land T, Fatal and Nonfatal Overdose Among Pregnant and Postpartum Women in Massachusetts, *American College of Obstetricians and Gynecologists*, 2018;132(2):466–474.

continuing treatment, and receiving supportive services across the continuum of care.[42] Such barriers may include: program availability and/or capacity; limited access to family-centered treatment with integrated supports; limited care and long-term supports for infants born with NAS; and/or limited transportation, housing, and employment supports. [43] Women may also encounter psychosocial barriers, such as societal bias and stigma.[44]

34. As a result of the potential treatment barriers, it is critical that healthcare workers who provide care for women with substance use disorders receive additional training so as to understand health workers providing care for women with substance use disorders during pregnancy need to understand the complexity of the woman's social, mental and physical problems and to provide the right advice and support throughout pregnancy and the postpartum period.[45]

35. Creating and enhancing programs for postpartum women is also important. The first year postpartum is a very vulnerable time for women with opioid use disorder, and, as noted above, is associated with a high risk of an overdose event.[46]

D. Neonatal Abstinence Syndrome

36. From 2004 and 2014, the diagnosis of opioid abuse or dependence among delivering mothers in Ohio grew by 491 percent.[47] One of the consequences of the increasing rate of maternal opioid use disorder is an increase in neonatal abstinence syndrome (NAS), a syndrome that may occur in opioid-exposed newborns shortly after birth.[48]

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[42] Center for Substance Abuse Treatment. Substance Abuse Treatment: Addressing the Specific Needs of Women: Treatment Improvement Protocol (TIP) series 51; vol HHS publication no. (SMA) 09-4426. Rockville, MD: Substance Abuse and Mental Health Services Administration; 2009. Cleveland, Lisa & Bonugli, Rebecca. (2014). Experiences of Mothers of Infants with Neonatal Abstinence Syndrome in the Neonatal Intensive Care Unit. *Journal of Obstetric, Gynecologic, and Neonatal Nursing : JOGNN / NAACOG*. 43. 10.1111/1552-6909.12306

[43] *Ibid*.

[44] Cleveland, *JOGNN / NAACOG* (2014).

[45] World Health Organization: Guidelines for Identification and Management of Substance Use and Substance Use Disorders in Pregnancy. October 2014. Available at http://www.who.int/substance_abuse/publications/pregnancy_guidelines/en/.

[46] Schiff, *American College of Obstetricians and Gynecologists* (2018).

[47] Massatti, R., Falb, M., Yors., Potts, L., Beghly, C. & Starr, S., (2013, November) Neonatal abstinence syndrome and drug use among pregnant women in Ohio, 2004-2011. Columbus, OH: Ohio Department of Mental Health and Addiction Services.

[48] Hudak, *Pediatrics*. 2012.

37. Neonatal abstinence syndrome is a clinical diagnosis given to infants who experience withdrawal signs and symptoms after in utero exposure to opioids. Withdrawal signs develop in 55% to 94% of opioid exposed infants, with 30-65% of those infants requiring pharmacologic treatment for severe withdrawal.[49,50,51]

38. The clinical signs of NAS result from central nervous system hyper excitability and autonomic instability. NAS signs can begin within 24 hours of birth after heroin exposure, within 48 hours for short acting prescription opioids, and up to 72 to 96 hours after birth for newborns exposed to long acting opioids such as methadone and buprenorphine.[52] The most prominent signs in NAS are tremors, poor feeding, excessive crying, loose stools, poor sleeping, and hyperirritability. Other signs of NAS include sneezing, yawning, hiccups, myoclonic jerks, skin breakdown and abrasions, vomiting, nasal stuffiness, and seizures in the most severe cases.[53]

39. Over the last two decades, the US incidence of NAS has sharply increased from 1.19 per 1000 hospital births in 2000, to 5.63 in 2012.[54] During that same time period, the number of infants treated for the syndrome in US neonatal intensive care units increased five-fold.[55]

[49] Hall, *Pediatrics* (2014).

[50] Patrick, *JAMA* (2012).

[51] Hudak, *Pediatrics* (2012).

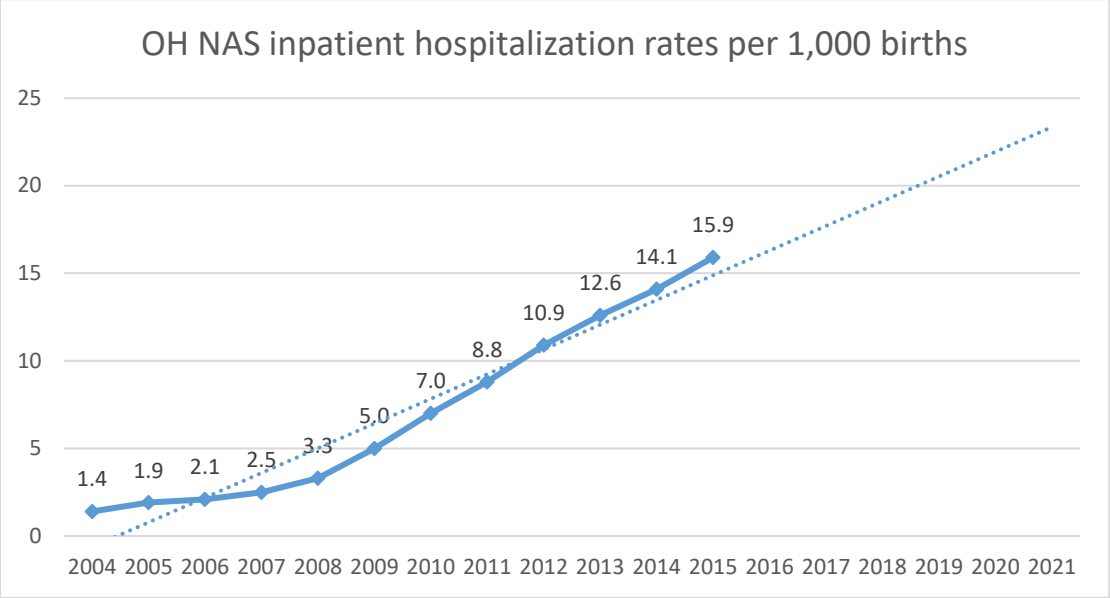
[52] Hall, *Pediatrics* (2014); Hudak, *Pediatrics* (2012).

[53] Hudak, *Pediatrics*, (2012).

[54] Patrick, *JAMA* (2012).

[55] Patrick, *Journal of Perinatology* (2015).

1. The Rapidly Increasing Rate of NAS in Ohio



40. Between 2006 and 2015, there were 11,283 hospitalizations resulting from Neonatal Abstinence Syndrome (NAS) in inpatient settings in Ohio. According to the Ohio Department of health, "in 2015 alone, there were 2,174 admissions, which equates to nearly six admissions per day."

41. The diagnosis of NAS continues to increase across the State of Ohio. Since 2012, over 1% off all deliveries in Ohio had the diagnosis of NAS. This rate is projected to be above 2% in the year 2020.[56]

42. The reason for this increase of babies diagnosed with NAS is multifactorial. Notably, the increase in the number of women of childbearing age with opioid use disorder has exposed more babies in utero to opioids.

[56] Health ODo. 2017 Ohio Neonatal Abstinence Syndrome Report. *Online*. Dec. 11, 2018. Available at https://odh.ohio.gov/wps/portal/gov/odh/know-our-programs/violence-injury-prevention-program/media/2017_nas_county_table.

2017 Ohio Neonatal Abstinence Syndrome Report

Table 1: Hospitalizations* Among Ohio Resident Newborns for Neonatal Abstinence Syndrome, 2006-2017**

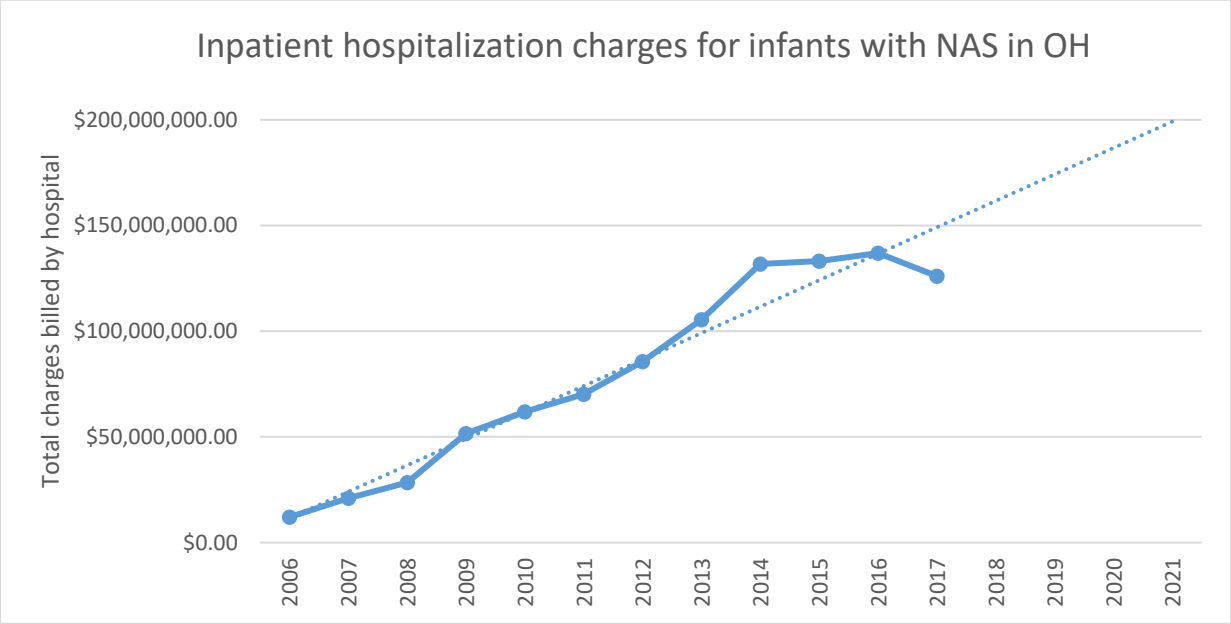
Neonatal Abstinence Syndrome	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
Neonatal Abstinence Syndrome inpatient discharges	305	369	477	715	953	1172	1482	1717	1919	2174	2223	1935
Medicaid Discharge	222	288	369	583	811	998	1322	1502	1741	1950	1986	1753
Non-Medicaid Discharge	83	81	108	132	142	174	160	215	178	224	237	182
Average length of days (LOS) in days	16	19.5	20.1	19.6	18.9	16.37	17.73	15.19	14.9	13.9	12.9	13.41
Total LOS (days)	4,892	7,200	9,580	14,006	17,965	19,181	21,834	26,085	28,580	30,153	28,656	25,954
Average charge***	$39,561	$59,033	$59,580	$72,158	$64,911	$59,847	$57,813	$61,469	$68,666	$61,241	$61,598	$65,127
Total charge***	$12,066,087	$20,982,542	$28,419,546	$51,592,956	$61,860,258	$70,140,821	$85,678,946	$105,542,816	$131,770,486	$133,138,341	$136,932,674	$126,020,134

*Hospitalizations occurred in Ohio hospitals to Ohio residents
**NAS reflects ICD-9 CM code 779.5 for 2006 - 9/30/2015 and ICD-10-CM code P96.1 for 10/01/2015 - 2016 (NAS-Could be in primary or 18 secondary dx fields)
***Charges reflect charges billed by the hospital

Table 2: Births* to Ohio Residents in Ohio Hospitals, 2006-2017

Hospital Births	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
Hospital births inpatient discharges	152,740	151,454	148,800	146,226	139,987	137,168	139,517	140,034	140,656	140,658	140,142	138,267
Medicaid Discharge	60,976	59,830	61,461	65,062	63,710	62,429	67,364	65,415	67,308	67,009	63,792	64,808
Non-Medicaid Discharge	91,764	91,624	87,339	81,164	76,277	74,739	72,153	74,619	73,348	73,649	76,350	73,459
Average LOS (days)	3.4	3.5	3.5	3.6	3.6	3.6	3.8	3.7	3.7	3.7	3.7	3.8
Average charge**	$6,838	$7,870	$8,660	$9,680	$10,336	$11,452	$12,977	$13,604	$14,570	$15,494	$16,695	$17,812

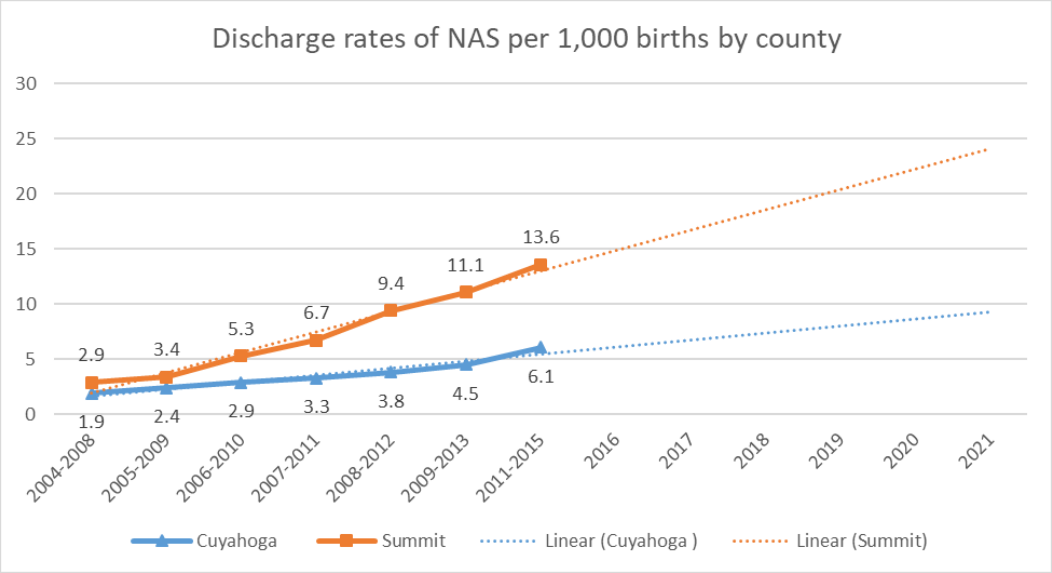
*Hospital births reflect MSDRG codes 789-795 (Neonates and Newborns)
**Charges reflect charges billed by the hospital



43. Inpatient hospitalization for NAS infants corresponds to costly hospital expenditures – many of which are often shouldered by state Medicaid programs.

2. The Rates of NAS in Cuyahoga and Summit Counties

44. In Cuyahoga County for the year 2017 there were 137 infants diagnosed with NAS, and in Summit County there were 71 infants. For the five-year period of 2013-2017, a total of 629 infants in Cuyahoga County and 426 infants in Summit County were diagnosed with NAS. Summit County is projected to have more than 2% of all births with the diagnosis of NAS by 2020.[57]



3. Standard Treatments and Interventions for NAS

45. Babies born to mothers who use or are addicted to opioids need particular care and attention. By improving and standardizing the care these babies receive, OPQC expects to reduce the length of hospital stay for newborns and improve outcomes at discharge.

46. Given the underreporting of maternal drug use, traditional risk-based screening methods may not identify all newborns at risk for NAS and therefore underestimate in utero opioid exposure.[58,59] Universal maternal drug testing improves the identification of infants at risk for the development of NAS. After adoption of universal maternal testing, the Cincinnati region has had a decrease in need for pharmacologic treatment for opioid-exposed infants

[57] *Ibid*.

[58] Wexelblatt, *The Journal of Pediatrics* (2015).

[59] Hall ES, Wexelblatt SL, Greenberg JM. Self-reported and Laboratory Evaluation of Late Pregnancy Nicotine Exposure and Drugs of Abuse. *Journal of Perinatology : Official Journal of the California Perinatal Association*. 2016;36(10):814-818.

to 30% (unpublished data CCHMC NAS Task Force), compared to a statewide level of 42%.[60]

47. There is no nationally recognized protocol for treatment, leading to substantial variation in practice, degree of opioid exposure and hospital length of stay. Through our statewide collaborations of OCHA and OPQC, we have created a standardized protocol to safely decrease the length of stay.[61]

    (1) All infants are scored every 3-4 hours around feedings with the modified Finnegan Scoring System. This scoring tool is performed by nurses and addresses 21 different components.

    (2) Nonpharmacologic treatment measures, including swaddling, skin-to-skin care, rooming in, and reduced stimulation are recommended.[62,63]

    (3) Pharmacologic treatment support with opioids, such as morphine or methadone, has been shown to be the best treatment when medication is needed.[64,65,66] Initiation of medication is done based on worsening withdrawal despite nonpharmacologic interventions. The updated protocol is attached as **Exhibit B** to this report.[67]

48. Per OPQC data, the average overall length of stay for the 9,648 opioid exposed infants was 8.6 days during the period of 2014-2018. The proportion of infants requiring

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[60] Ohio Perinatal Quality C. OPQC Neonatal Abstinence Syndrome Project. 2018; https://opqc.net/sites/bmidrupalpopqc.chmcres.cchmc.org/files/NAS/AP%20Calls/OPQC%20NAS%20Sustain%206.19.18.pdf

[61] Hall, *Pediatrics* (2014); Hall, *Pediatrics* (2015); Walsh, *Pediatrics* (2018)

[62] Holmes AV, Atwood EC, Whalen B, et al. Rooming-In to Treat Neonatal Abstinence Syndrome: Improved Family-Centered Care at Lower Cost. *Pediatrics*. 2016;137(6).

[63] Howard MB, Schiff DM, Penwill N, et al. Impact of Parental Presence at Infants' Bedside on Neonatal Abstinence Syndrome. *Hospital Pediatrics*. 2017;7(2):63-69.

[64] Wexelblatt SL, McAllister JM, Nathan AT, Hall ES. Opioid Neonatal Abstinence Syndrome: An Overview. Clinical pharmacology and therapeutics. 2018;103(6):979-981.

[65] Kraft WK, Stover MW, Davis JM. Neonatal abstinence syndrome: Pharmacologic strategies for the mother and infant. *Seminars in perinatology*. 2016;40(3):203-212.

[66] Disher T, Gullickson C, Singh B, et al. Pharmacological Treatments for Neonatal Abstinence Syndrome: A Systematic Review and Network Meta-analysis. JAMA Pediatr. 2019.

[67] Ohio Perinatal Quality C. OPQC Recommended NAS Protocol Changes 2017. 2017. Available at https://opqc.net/sites/bmidrupalpopqc.chmcres.cchmc.org/files/NAS/OPQC%20Recommended%20NAS%20Protocol%20Changes%202017.pdf

pharmacologic treatment declined 6% from 48% to 42%, (about 134 infants/year statewide). For infants requiring pharmacologic treatment, the days of opioid treatment declined from 14.6 to 12.2 days, and length of stay declined from 18.2 to 16.2 days.[68]

49. There are lasting effects on children diagnosed with NAS. Infants with opioid exposures are more likely than infants with no drug exposures to be diagnosed with: behavioral or emotional disorders, developmental delay, lower developmental scores, speech disorder, strabismus, increased incidence of torticollis and associated plagiocephaly, and more likely to be exposed to the hepatitis C virus.[69,70]

50. Closer follow up is needed for opioid exposed infants compared to non-exposed due to the potential long-term complications stated above. [71]

51. Continued observation of opioid-effected children will be important in order to ensure optimal outcomes among this population, particularly given the potential that delays observed at two years of age may predict later learning disabilities or increased risk of addiction.[72] Early intervention has been shown to help in childhood,[73] and should be provided to those infants with a NAS diagnosis.

4. Long-Term Care for Children and Families Impacted by Opioids

52. There are several emerging models for the long-term care of children and families impacted by opioids. Models providing family-centered care, comprehensive pediatric care, and developmental follow-up have all been demonstrated to improve outcomes.

53. Family-centered care involves providing direct pediatric care to opioid-exposed children, as well as direct medical and addiction care for parents in recovery. Such care can provide

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[68] Ohio Perinatal Quality C. OPQC Neonatal Abstinence Syndrome Project. 2018. Available at https://opqc.net/sites/bmidrupalpopqc.chmcres.cchmc.org/files/NAS/AP%20Calls/OPQC%20NAS%20Sustain%206.19.18.pdf.

[69] McAllister JM, Hall ES, Hertenstein GER, Merhar SL, Uebel PL, Wexelblatt SL. Torticollis in Infants with a History of Neonatal Abstinence Syndrome. *The Journal of Pediatrics*. 2018;196:305-308.

[70] Merhar SL, McAllister JM, Wedig-Stevie KE, Klein AC, Meinzen-Derr J, Poindexter BB. Retrospective review of neurodevelopmental outcomes in infants treated for neonatal abstinence syndrome. *Journal of Perinatology : Official Journal of the California Perinatal Association*. 2018;38(5):587-592.

[71] McAllister, *Journal of Pediatrics* (2018); Merhar, *J of Cal. Perinatal Asso*. (2018).

[72] Health ODo. 2017 Ohio Neonatal Abstinence Syndrome Report. 2018; https://odh.ohio.gov/wps/portal/gov/odh/know-our-programs/violence-injury-prevention-program/media/2017_nas_county_table

[73] Cannon JS, Kilburn MR, Karoly LA, Mattox T, Muchow AN, Buenaventura M. Investing Early: Taking Stock of Outcomes and Economic Returns from Early Childhood Programs. *Rand Health Q*. 2018;7(4):6.

a continuum of interdisciplinary services integrated with primary health care. Potential services may include home visiting, case management, child developmental monitoring, speech and language, physical therapy, and occupational therapy, infant mental health services, referrals to legal services, and community referrals. Residential care for pregnant women with substance use disorders is another important component of family-centered care. Women may be able to stay at the residential facilities postpartum in order to continue to receive supportive services.

54. Comprehensive pediatric care programs provide multidisciplinary, long-term care for all pediatric needs, with possible links to adult care for parents. These programs seek to provide comprehensive long-term pediatric care from birth to adulthood.

55. Pediatric developmental follow-up programs provide longitudinal developmental assessment and support while pediatric primary care and other care takes place elsewhere.

5. Current Ohio Initiatives Relating to NAS

56. In response to the growing rates of NAS, Ohio implemented and tested models of care for pregnant women with opioid use disorder through a project known as Maternal Opiate Medical Supports (MOMS).

57. Compared to the Medicaid comparison cohort, MOMS pilot site participants: received more prenatal care visits; received more behavioral health services during pregnancy and after delivery; had fewer foster care placements and fewer cases of substantiated or indicated abuse and neglect.[74]

58. In collaboration with the Ohio Department of Mental Health and Addiction Services (ODHMAS), the Ohio Department of Medicaid (ODM), and the Ohio Department of Health (ODH), OPQC has built on the initial MOMS project through its MOMS+ initiative. Through MOMS+, OPQC aims to optimize the maternity medical home and to improve outcomes for pregnant women with opioid use disorder and their infants.

59. The goal of MOMS+ is to improve care and outcomes by supporting maternity care providers in the care of pregnant women with opioid use disorder, working closely with those who provide medication assisted treatment and behavioral health therapy.

60. The Cincinnati Children's Hospital provides a pediatric developmental follow-up program to substance-exposed infants in the region through its Neonatal Abstinence Syndrome

[74] Presentation by Michele Walsh, MD and Michael Marcotte, MD, IHI National Forum Presentation, December 11, 2018. Available at http://app.ihi.org/FacultyDocuments/Events/Event-3135/Presentation-17169/Document-14004/Presentation_C5__Improve_Outcomes_for_Moms_and_Babies_Marcotte.pdf

Clinic ("NAS Clinic). The NAS Clinic is one of the few clinics in the nation that follows substance-exposed infants over time. The Hospital's NAS Clinic provides developmental screening, occupational and physical therapy, and education about nutrition and feeding to substance-exposed infants up to the age of two years old. The clinic is staffed by physicians, neonatal nurse practitioners, nurses, nutritionists, social workers, occupational therapists, speech therapists, and physical therapists, who provide multidisciplinary care during infants' regular visits with their physicians. A social worker also meets with patients during clinic visits, addressing broad social needs including those of children in foster care placement. Children receive vision screens at six to eight months of age. Hepatitis C testing is done for infants with prenatal exposure to the virus. The NAS team also provides outreach and education in groups to mothers during pregnancy and postpartum.

IV. RECOMMENDATIONS FOR IMPROVING OUTCOMES

As set forth above, it is my opinion that the increasing number of women with opioid use disorder in Cuyahoga and Summit Counties, as well as growing incidence of NAS, is a significant public health issue. In order to address this urgent issue and improve outcomes, the Counties should develop and enhance multidisciplinary programs and services for early intervention, prevention, and support. Women with opioid use disorder need intensive support during their pregnancy, delivery and postpartum period. Infants diagnosed with NAS need treatment to ween them off of opioids and continuing care to minimize lasting effects. It is my professional opinion that the programs and interventions suggested below would help to reduce opioid use among women who are or will become pregnant, reduce foster placements, and reduce the risk of potential harms to infants and children:

A. Prevention

- ✓ Create and/or support programming within opioid maintenance clinics that is designed to delay pregnancy until a prospective mother's health and dependence are improved;
- ✓ Educate women of childbearing age about substance abuse prevention;
- ✓ Establish community referral sources and services for pregnant women who are diagnosed with opioid use disorder and/or overdose including emergency rooms, women health clinics, community drug treatment centers among others;
- ✓ Provide counseling for women of childbearing age being treated for substance abuse or dependence on the impact of substance use on pregnancy;
- ✓ Implement the use of standardized screening tools early in prenatal care;
- ✓ Implement programs to improve and expand screening to identify women in need of intervention and treatment referral;

- ✓ Screen for substance abuse as part of a comprehensive obstetric care plan at first prenatal visit in partnership with the pregnant woman to identify infants at risk for the development of NAS;

- ✓ Create public education campaigns to raise awareness of the health effects of opioid use prior to and during pregnancy;

- ✓ Invest resources in public education campaigns that aim to reduce barriers for women seeking treatment prior to conception and/or in early pregnancy by encouraging women to seek prenatal care and avoiding criminalizing pregnant women with opioid addiction.

B. Education and Training

- ✓ Educate physicians and nurses who treat women about the signs of addiction and utilize standardized screening tools for at-risk women;

- ✓ Enhance training for providers caring for pregnant women with opioid use disorders to understand the complexity of the woman's social, mental and physical problems ;

- ✓ Provide medical providers with training and need for screening tools early in prenatal care in order to identify pregnant women in need of treatment and/or other supportive services.

C. Supportive Services and Interventions

- ✓ Expand existing MAT treatment programs and develop supportive services to mitigate potential barriers to these services including program availability, capacity, and transportation;

- ✓ Develop programs that provide coordinated services between MAT providers, perinatal healthcare providers, and specialists in addiction medicine, behavioral health, and social services;

- ✓ Eliminate barriers to buprenorphine replacement therapy during pregnancy, which can decrease the severity of newborn withdrawal, allowing certified providers to increase the number of patients they are treating;

- ✓ Provide intensive support to mothers during pregnancy, delivery, and postpartum period. Including outpatient program for pregnant women with an available overnight housing unit providing substance abuse treatment, psychiatry, medical treatment and family planning;

- ✓ Implement coordinated care and connect mothers with outpatient support and treatment programs prior to discharge;

- ✓ Provide postpartum long-term addiction care;

- ✓ Provide aftercare services so mothers can cope with their addiction and learn about the special needs of their infants;
- ✓ Create additional residential treatment facilities for both the mother and infant;
- ✓ Provide family based care to opioid exposed children as well as direct care for parents in recovery or maintenance;
- ✓ Ensure nurseries develop standardized evidence-based policies to assess and treat infants with NAS;
- ✓ Provide support to families to improve the outcomes for infants with NAS through breastfeeding, visits, and other support;
- ✓ Create pediatric developmental follow-up programs for opioid exposed infants.

V. DISCLOSURES AND RESERVATION OF RIGHTS

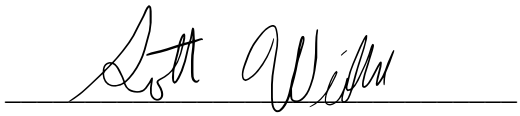
61. This report contains a true and accurate statement of my opinions in this matter. The matters cited in this expert report are based on my personal knowledge, education, and years of industry experience and, if called to testify, I will testify to the same effect.

62. This report is a statement of opinions I expect to express in this matter and the basis and reasons for those opinions. This report summarizes only my current opinions and analyses to date, which are subject to change depending upon ongoing discovery and additional information. I respectfully reserve the right to supplement my report in light of this and any other additional fact discovery, opinions by other experts, and/or trial testimony. I also respectfully reserve the right to provide rebuttal opinions and testimony in response to other experts, and rebuttal testimony in response to any fact witnesses. In connection with my anticipated trial testimony in this action, I may use as exhibits various documents produced in this litigation that refer to or relate to the matters discussed in this report. In addition, I respectfully reserve the right to use animations, demonstratives, enlargements of actual attachments, and other information in order to convey my opinions.

63. I understand that I may be asked to provide further opinions and analyses on other issues, including in response to analyses provided by other experts. I will do so at the appropriate time set by the Court.

64. The opinions in the report are stated to a reasonable degree of medical certainty in the field of the pediatrics and maternal-fetal issues as they relate to exposure and impact of in utero opioid exposure to infants.

Executed on this 25th day of March, 2019, in Mason, Ohio.



Scott Wexelblatt M.D.

Exhibit A

Scott L. Wexelblatt M.D.
3795 Riverside Drive
Mason, OH 45040
(513) 300-6432

Education:

Board Certification:
American Board of Pediatrics, October 1999
Recertified in 2007, 2014.

Medical License:
State Medical Board of Ohio

Postgraduate Training:
Cincinnati Children's Hospital Medical Center
Pediatric Residency and Internship
Program Director: Dr. Michael Farrell
July 1996- June 1999

Medical Degree:
University of Vermont College of Medicine
Burlington, VT
August 1992-May 1996

Bachelor of Arts:
University of Delaware
Newark, DE
BA: Psychology
September 1988-May 1992
Phi Beta Kappa
Golden Key National Honor Society
Cum Laude

Academic Appointment:

- Associate Professor of Pediatrics, University of Cincinnati College of Medicine. (2017-present)
- Assistant Professor of Pediatrics, University of Cincinnati College of Medicine. (2008-2017)
- Cincinnati Children's Hospital Medical Center, Perinatal Institute, Division of Neonatology. (1999-present).

Memberships:

- Society for Pediatric Research. Member. 2015-present.

Leadership and Management:

- Medical Director for Newborn Care Associates, which is a 60+ physician group that provides 24-hour coverage to 14 area hospitals.
- Medical Director Special Care Nursery, Bethesda North Hospital (2009-present)
- Medical Director, Department of Pediatrics, Bethesda North Hospital (2009-present)
- Medical Director, West Chester Hospital Newborn Services (2014-2015)
- Perinatal Institute Neonatal Task Force. Leader of this regional 14-hospital task force to standardize the treatment for drug exposed infants. (2012-present)

Clinical Activities:

I am an attending physician at the level 1 and 2 nurseries at Bethesda North Hospital, West Chester Hospital, Mercy Fairfield Hospital, Mercy West Hospital, Mercy Anderson Hospital, Fort Hamilton Hospital, Soin Medical Center, and Southview Hospital. I also attend in the level 1 nursery at University Hospital, Kettering Medical Center, and Good Samaritan Hospital.

I am responsible for all high-risk deliveries that occur at the level 2 hospital, and for the care of all infants requiring a higher level of care in the Special Care Nursery.

Service and Citizenship:

Committee Involvement:

- Ohio Perinatal Quality Collaboration (OPQC) for the Neonatal Abstinence Syndrome project. Faculty member, 2013-present.
- Hamilton County Opiate Healthcare Response Committee. Physician representative. 2016-present.
- Perinatal Institute Quality Improvement Steering Committee member. 2014-present
- Perinatal Institute Epic Task Force. Former lead, now member for the task force to standardize the Epic use for our six different Epic versions at our regional level 1 and 2 nurseries. 2013-present
- Ohio Children's Hospital Collaboration (OCHA) for Neonatal Abstinence Syndrome. Regional Clinical Lead, 2012-present
- Bethesda North OB/GYN Quality Assurance Team. Member. 2014-present.
- Medical Student interview MMI facilitator. 2018-present.
- Problem Based Learning and Practice Improvement Conference at Bethesda North Hospital (Formerly Perinatal Morbidity and Mortality Committee). Department lead. 2006-present
- Cincinnati Committee of Perinatal Outreach Program (CCPOP). Member. 2010-2014.
- Catholic Health Partners, Perinatal Clinical Advisory Team. Neonatal Chairperson. 2010-present.
- Perinatal Safety Team. TriHealth. Member. 2011-present.
- Quality Focus Team for Leadership. TriHealth. Member. 2011-present.
- Bethesda North OB/Anesthesia Quality Team. Department lead. 2011-present.
- Cincinnati Children's Home Care Advisory Committee. Advisor. 2012-present
- Advanced Improvement Leadership Systems, Cincinnati Children's Hospital. Member. 2011.

National Activities:

- Invited to Health Human Services National Convening on Neonatal Abstinence Syndrome. Philadelphia. October 2018.
- Speaker for Invited Lecture Series at Pediatric Academic Society Annual Meeting. Achieving the triple aim for opioid-exposed newborns: Innovations in high quality, high-value, family-centered care for neonatal abstinence syndrome (NAS). San Francisco CA, April 2017.
- Speaker at National Rx Drug and Heroin Abuse Summit. Universal Maternal Drug Testing. April 2017.
- Speaker at National Rx Drug and Heroin Abuse Summit. Universal Maternal Drug Testing. April 2016.
- Speaker at platform presentation. Pediatric Academic Societies Annual Meeting, San Diego, CA. Collaboration between WIC and EHDI to Improve Follow-Up of Newborn Hearing Screening in Greater Cincinnati. April 2015.
- Speaker on behalf of the OCHNAS Consortium at a poster symposium. Pediatric Academic Societies Annual Meeting, San Diego, CA, April 2015. Neonatal Abstinence Syndrome: Adoption of a Stringent Weaning Protocol in a Multicenter Cohort.
- Speaker at National Rx Drug Abuse Summit. Neonatal Abstinence Syndrome. April 2015. Atlanta, GA.

Manuscript review: I have reviewed papers for Journal of Pediatrics, BMC Pediatrics, Pediatrics, Hospital Pediatrics, and Pediatric Quality and Safety. I review an average of 6 papers per year.
Recruitment: I am actively involved in the interviewing of faculty candidates, staff physicians, and part-time hires for the division of Neonatology.
Activities:

- Physician representative on the build team for Mercy Fairfield Hospital design of a new level 2 Special Care Nursery.
- Member of the design and build team for Mercy West Hospital for a new level 2 hospital that opened in 2013.
- Physician champion for the Special Care Nursery at Bethesda North Hospital and Mercy Fairfield Special Care Nursery fundraising.
- Key member in the development of the division statements on: car seat challenges, guidance during shortage of Erythromycin ophthalmic ointment, care of infants born to mothers with influenza, and Synagis recommendations

Teaching and Mentoring:

- Mentor to family practice residence, pediatric residence, hospitalist fellows, medical students, and nurse practitioner students during their newborn rotation.
- Graduated from Intermediate Improvement Science Series (I2S2). Project: “Reducing Readmissions Secondary to Hyperbilirubinemia”. April 2010-November 2010.

Presentations/Invited Lectures:

- Tri-State Opioid Symposium. Neonatal Abstinence Syndrome. Cincinnati, OH. March 2019.
- Ohio Chapter of the American Academy of Pediatrics Annual meeting. *Neonatal Abstinence Syndrome*. Columbus, OH. September 2018.
- Tackling the Ohio Opioid Crisis: Harnessing the Power of Science to Break the Cycle. University of Cincinnati. Cincinnati, OH. November 2017.

- Ohio State University OB/GYN Grand Rounds. *Universal Maternal Drug Testing*. Columbus, OH. November 2017.
- Ohio Chapter of the American Academy of Pediatrics Annual meeting. *Neonatal Abstinence Syndrome*. Columbus, OH. October 2017.
- Mercy Perinatal Conference. *Universal Maternal Testing and Neonatal Abstinence Syndrome*. Toledo, OH. March 2017.
- Massachusetts Perinatal Quality Collaboration. *Improving the Care of the Opioid Exposed Infant*. November 2016.
- AWHONN Ohio Section Conference. *Universal Maternal Testing*. Cincinnati, OH. September 2016.
- Cincinnati Pediatric Society's Pediatric Intensive: *Neonatal Abstinence Syndrome*. October 2015
- Pediatric Grand Rounds, Cincinnati Children's Hospital Medical Center. *Neonatal Abstinence Syndrome.* August 2015.
- Tennessee Perinatal Quality Collaboration: Neonatal Abstinence Syndrome. February 2015.
- Neonatal Grand Rounds, Cincinnati Children's Hospital Medical Center. *Neonatal Abstinence Syndrome.* November 2014
- Ohio Chapter, American Society of Addiction Medicine Annual Meeting. *Neonatal Abstinence Syndrome.* August 2014.
- AWHONN Ohio Section Conference. *Neonatal Abstinence Syndrome*. September 2013.
- Pediatric Grand Rounds, Cincinnati Children's Hospital Medical Center. *Neonatal Abstinence Syndrome.* May 2013.
- Greater Cincinnati Health Council. *Neonatal Abstinence Syndrome*. October 2012-May 2013. Talks at 12 regional birthing hospitals about universal maternal testing.
- Perinatal Grand Rounds, Kettering Health Network. *Neonatal Abstinence Syndrome.* November 2012.
- Hospital-based Regional Perinatal Social Work Meeting. *Neonatal Abstinence Syndrome.* November 2012.
- Neonatology Grand Rounds, Cincinnati Children's Hospital, August 2007, *Rare Images in Neonatology: Interesting Cases in Newborn Nurseries.*
- Mercy Fairfield Hospital. Late Preterm Symposium. *The Late Preterm Infant Morbidity and Mortality. Feb 2011*
- Neonatology Grand Rounds, Cincinnati Children's Hospital, October 2009, *Impacting Regional Newborn Care: Care seat Challenge.*

Research and Scholarly Activity:

Funded Research:

- Ohio Department of Medicaid. Ohio Opioid Analytics Project – Child Welfare. G1819050094. Wexelblatt (PI). 05/14/18 – 06/30/19. Role: Primary Investigator. 10% effort.
- NIH/NIDA. Ohio Valley Node-Network (OVNN) of the NIDA Clinical Trials Network. UG1 DA013732. Winhusen (PI). 06/01/18 – 05/31/20. Role: Primary Investigator. 10% effort.

Completed Research Support

- Ohio Department of Job and Family Services. University Hospital Case Medical Center The Ohio Children's Hospital Research Consortium: Neonatal Abstinence Syndrome. G1213070561. Wexelblatt (PI). 07/01/12 – 6/30/2019. Role: Primary Investigator

- CDC, Maternal and Child Health (MCH) Disability Research Center. 5U01DD001007. Hunter/Wexelblatt. 10/01/13-9/30/15. Collaboration between WIC and EHDI to Improve Follow-up of Newborn Hearing Screening in Greater Cincinnati. Role: co- Primary Investigator. Funding by CDC. 5% effort, peer reviewed.

Publications:
Peer reviewed publications:

- Developmental Disorders and Medical Complications Among Infants with Subclinical Intrauterine Opioid Exposures. Hall ES, McAllister JM, **Wexelblatt SL**. Popul Health Manag. 2018 Jun 12. PMID: 29893624.

- Ohio Perinatal Quality Collaborative Improves Care of Neonatal Narcotic Abstinence Syndrome. Walsh, M; Crowley, M; **Wexelblatt, S**; Ford, S; Kuhnell, P; Kaplan, H; McClead, R; Macaluso, M; Lannon, C. Pediatrics. In Press. 2018. PMID: Pending.

- Surveillance of Intrauterine Opioid Exposures Using Electronic Health Records. Hall ES, **Wexelblatt SL**, Greenberg JM. Popul Health Manag. 2018 Feb 27. PMID: 29485940.

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Wexelblatt
Trial Deposition Testimony

Date	Case	Court/State	Case Number	Attorney (Firm)	Action
Nov, 2017	Sanner vs Poutous and Price	Allegheny County, Pennsylvania	GD 15-19224	Dickie/McCamey	Deposition
Dec, 2016	Freshwater vs Trinity	Court of Common Pleas Jefferson, OH	15-CV-00473	Mel O'Brien (Dickey/McCamey)	Deposition

Wexelblatt
Trial Deposition Testimony
Exhibit A

Date	Case	Court/State	Case Number	Attorney (Firm)	Action
Nov, 2017	Sanner vs Poutous and Price	Allegheny County, Pennsylvania	GD 15-19224	Dickie/McCamey	Deposition
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Exhibit B

The Ohio Perinatal Quality Collaborative

Updates/changes to the recommended OPQC NAS Protocol

<u>Introduction</u>: These protocols are a synthesis of the best available, although limited evidence, and an analysis of practice variation across the state of Ohio in a cohort of over 6800 term infants (>=37 weeks GA) with maternal narcotic exposure. The updated methadone protocol is based initially on pharmacokinetic data [13] and then subsequent published improvement with implementation of the protocol [14]. Changes from the Ohio Children's Hospital Association (OCHA - pilot project) [9] recommended protocol include:

- The non-pharmacological treatment formula feeding recommendation is based upon OPQC's QI initiative using a factorial design testing the impact of formula (LLF vs. No LLF and 22 kcal vs. 19 kcal) on care of infants with NAS.

- The Methadone updates are based on a pharmacokinetic informed protocol that demonstrated lower length of treatment and length of stay.

- Morphine updates include escalation/rescue doses that are *score based*.

- The pharmacological treatment updates are based on enteral dosing. IV dosing for Morphine differs and is included as a footnote in the rare occurrence an NAS infant is NPO.

- Phenobarbital is listed as the recommended secondary drug option. It is included in the protocol because centers have the most experience with it, but evidence is lacking for all secondary agents. Due to this fact, some centers may elect to use clonidine. Each center should select one agent and use the same drug consistently as an adjunct therapy. Should Clonidine be selected as the secondary medication of choice, it is NOT recommended that an infant be discharged home on the drug.

Exhibit B

The Ohio Perinatal Quality Collaborative

Ohio Perinatal Quality Collaborative:

Enteral Methadone or Morphine Protocol for

Neonatal Abstinence Syndrome (NAS) from Maternal Exposure

Introduction: These protocols are a synthesis of the best available, although limited evidence, and an analysis of practice variation across the state of Ohio in a cohort of over 6800 term infants (>=37 weeks GA) with maternal narcotic exposure. The updated methadone protocol is based initially on pharmacokinetic data [13] and then subsequent published improvement with implementation of the protocol [14].

These are viewed as potentially better protocols that humanely and safely wean infants off narcotics over a 2-3 week period.

Overview of Stages of treatment:

Non-pharmacologic bundle:	**Swaddle, skin to skin, decreased stimulation breast feed or 22kcal formula**
Pharmacologic bundle:	
• **Initiate**	• **Select Methadone or Morphine PO** • **Finnegan scores >8 q3hrs THREE times or scores ≥ 12 TWO times in a row**
• **Escalate**	• **If Finnegan scores remain elevated, increase dosage based on infant's score**
• **Stabilize**	• **Maintain dose for 24 hrs (Methadone)** • **Maintain dose for 48 hrs (Morphine)**

• **Wean**	• **Wean every 24 hrs based on Finnegan scores**
	  • **Wean by step daily (Methadone)**
	  • **Wean by 10% stabilizing dose daily (Morphine)**

• **Discharge**	• **Discharge 48 hrs off of Methadone or Morphine**

Exhibit B

The Ohio Perinatal Quality Collaborative

1. **Scoring: All Infants will be scored every 3-4 hours around feedings with the modified Finnegan Scoring System. Begin scoring prior to 12 hours of life.**

   1a. There are some experts who recommend using the *average* of Finnegan scores over a 24 hour period in the stabilization and weaning phase to minimize the impact of minor variations on dosing.

   1b. Centers should develop a plan for periodic refresher training for all nurses on the modified Finnegan scoring system using the D'Apolito Reliability Training system, and a training system for on-boarding new nursing staff. Recommend dual scoring to be done once a day minimum, in addition to periodic refresher training on the Finnegan scoring tools.

   1c. Adjust trigger scores when > 3 weeks old: Research has shown that NAS scores increase over time as the infant matures, so > 21 days all Trigger thresholds should be increased by 2.

2. Non-Pharmacologic Treatments: All infants with NAS will be treated with a bundle of non-pharmacologic interventions including decreased stimulation, swaddling, continuous holding and frequent feeds.

2a. Each institution should develop a policy for the use of Mother's Own Milk. Consideration of supporting breast feeding may be given if the mother is active in a treatment program and mother's addiction specialist supports breast feeding.

2b. If MBM is not used, use of a term 22kcal/oz formula to meet the exceptional caloric needs and combat the documented weight loss seen in NAS infants is recommended. Use of non-lactose containing formula is at the discretion of the individual unit. High calorie (22 kcal/oz) formula may be discontinued when the infant completes pharmacologic treatment or if the infant has excessive weight gain.

3. Pharmacologic Treatment: Each center should pick either Methadone or Morphine as their primary opioid for pharmacologic treatment and use this for ALL NAS infants treated in that center.

Exhibit B

The Ohio Perinatal Quality Collaborative

Methadone:

3a. NAS Methadone Initiation:

- **Start pharmacologic treatment for infants with 3 consecutive Finnegan scores > 8, or 2 consecutive Finnegan scores ≥ 12.**

	Methadone Dose	Dosing Interval	Number of Doses
Step 1	0.1 mg/kg	Q6	4
Step 2	0.07 mg/kg	Q12	2
Step 3	0.05 mg/kg	Q12	2
Step 4	0.04 mg/kg	Q12	2
Step 5	0.03 mg/kg	Q12	2
Step 6	0.02 mg/kg	Q12	2
Step 7	0.01 mg/kg	Q12	2
Step 8	0.01 mg/kg	Q24	1

3b. NAS Methadone Escalation:

- **If infant fails step 1 (scores >12) consider steps 1A through 1C.**

	Methadone Dose	Dosing Interval	Number of Doses
Step 1A	0.1 mg/kg	Q4	6
Step 1B	0.1 mg/kg	Q8	3
Step 1C	0.1 mg/kg	Q12	2

Adjunct Therapy/Second Drug: Phenobarbital

Phenobarbital is included in this protocol as the majority of sites had the most experience with it, but evidence is lacking for all secondary agents [12]. Due to this fact, some centers may elect to use clonidine. Each center should select one agent and use the same drug consistently as adjunct therapy.

Consider starting phenobarbital if:

- **Polysubstance exposure is suspected/confirmed: (benzodiazepines, barbiturates, antipsychotics, antidepressants, other sedatives/hypnotics, tobacco) AND**
  - **CNS findings predominate, rather than GI findings on NAS subscale e.g. tremors, increased muscle tone, etc.**
  - **Unable to wean for 2 consecutive days.**

Loading dose:

- **10 mg/kg/dose po every 12hr x 2 doses OR 20 mg/kg/dose x 1**
  - **Enteral formulation contains 10% alcohol.**
  - **Dividing po dose may decrease risk of emesis and/or sedation.**

Maintenance dose:

- **5 mg/kg/dose po once daily – do not adjust for weight**

Phenobarbital Wean: Two approaches may be used. (Neither has been directly studied.) Each center should pick one method.

- **A. Discontinue when on second to last step of morphine wean to assess for tolerance of discontinuation. Given long half-life of phenobarbital this will wear off gradually over 4 days.**
- **B. Discharging infant home on phenobarbital with subsequent weaning to be done either in Neo Clinic or by infant's PCP. (Given the high alcohol concentration limiting exposure may be the best practice. Hypnotic or nicotine withdrawal occurs rapidly and generally is completed by day 5- thus longer phenobarbital exposure may not be needed.)**

3c. NAS Methadone Weaning:

- **Wean to next step if average Finnegan score is < 8 for the past 24 hours.**
- **If average Finnegan score is 8-12, do not wean.**
- **If average Finnegan score is > 12, consider an extra dose of methadone at the current step, or return to the previous step.**

3d. NAS Methadone Discharge:

- **Observe for 48 hours off methadone.**

Exhibit B

The Ohio Perinatal Quality Collaborative

Morphine

4a. NAS Morphine Initiation: 0.05mg/kg/dose q3h po

4b. NAS Morphine Escalation

- **Increase dose every 3 hrs until controlled (average NAS ≤ 8 in 24 hours).**
- **Rescue Dose: If infant has 2 scores in a row of 9-12, increase Morphine by 0.02mg/kg/dose**
- **If infant has 2 scores in a row >12 increase morphine by 0.04 mg/kg/dose**
- **Please refer to Adjunct Therapy if dose becomes ≥0.3 mg/kg/dose**

Adjunct Therapy/Second Drug: Phenobarbital

Consider starting phenobarbital if:

- **Polysubstance exposure is suspected/confirmed: (benzodiazepines, barbiturates, antipsychotics, antidepressants, other sedatives/hypnotics, tobacco) AND**
  - **CNS findings predominate, rather than GI findings on NAS subscale e.g. tremors, increased muscle tone, etc.**
  - **Morphine dose exceeds 0.3 mg/kg/dose with NAS score > 8; OR unable to wean for 2 consecutive days.**

Loading dose:

- **10 mg/kg/dose po every 12hr x 2 doses OR 20 mg/kg/dose x 1**
  - **Enteral formulation contains 10% alcohol.**
  - **Dividing po dose may decrease risk of emesis and/or sedation.**

Maintenance dose:

- **5 mg/kg/dose po once daily – do not adjust for weight**

Phenobarbital Wean: Two approaches may be used. (Neither has been directly studied.) Each center should pick one method.

  - **A. Discontinue when on second to last step of morphine wean to assess for tolerance of discontinuation. Given long half-life of phenobarbital this will wear off gradually over 4 days.**

- **B. Discharging infant home on phenobarbital with subsequent weaning to be done either in Neo Clinic or by infant's PCP. (Given the high alcohol concentration limiting exposure may be the best practice. Hypnotic or nicotine withdrawal occurs rapidly and generally is completed by day 5- thus longer phenobarbital exposure may not be needed.)**

4c. NAS Morphine Stabilization

- **All scores remain ≤ 8 for minimum 48 hours.**
- **72 hours of stabilization may be used if infant has had to increase above 0.4mg/kg dose or if phenobarbital added.**

4d. NAS Morphine Wean and Backslide

- **Once stabilized on same dose for 48 hours, use this dose as the starting point of the wean.**
- **Begin weaning the dose by 10% (of the original dose when the first wean was started) every 24 hours.**
- **Drug may be discontinued when a single dose is < 0.02 mg/kg/dose. Please see below for example.**

Example:

Infant X (wt: 3.2 kg) required 2 dose increases of his morphine to get his NAS scores consistently ≤ 8. He has now been on the dose of 0.32 mg (0.1 mg/kg/dose) po q3hr for 72 hours. Team would like to begin weaning. As long as his scores remain consistently ≤ 8, please decrease by 10% every 24hrs.

Day 1: 0.29 mg q3hr (0.09 mg/kg)

Day 2: 0.26 mg q3hr (0.08 mg/kg)

Day 3: 0.22 mg q3hr (0.07 mg/kg)

Day 4: 0.19 mg q3hr (0.06 mg/kg)

Day 5: 0.16 mg q3hr (0.05 mg/kg)

Day 6: 0.13 mg q3hr (0.04 mg/kg)

Day 7: 0.1 mg q3hr (0.03 mg/kg)

Day 8: 0.06 mg q3hr (0.02 mg/kg) x 24hr and then stop

Exhibit B

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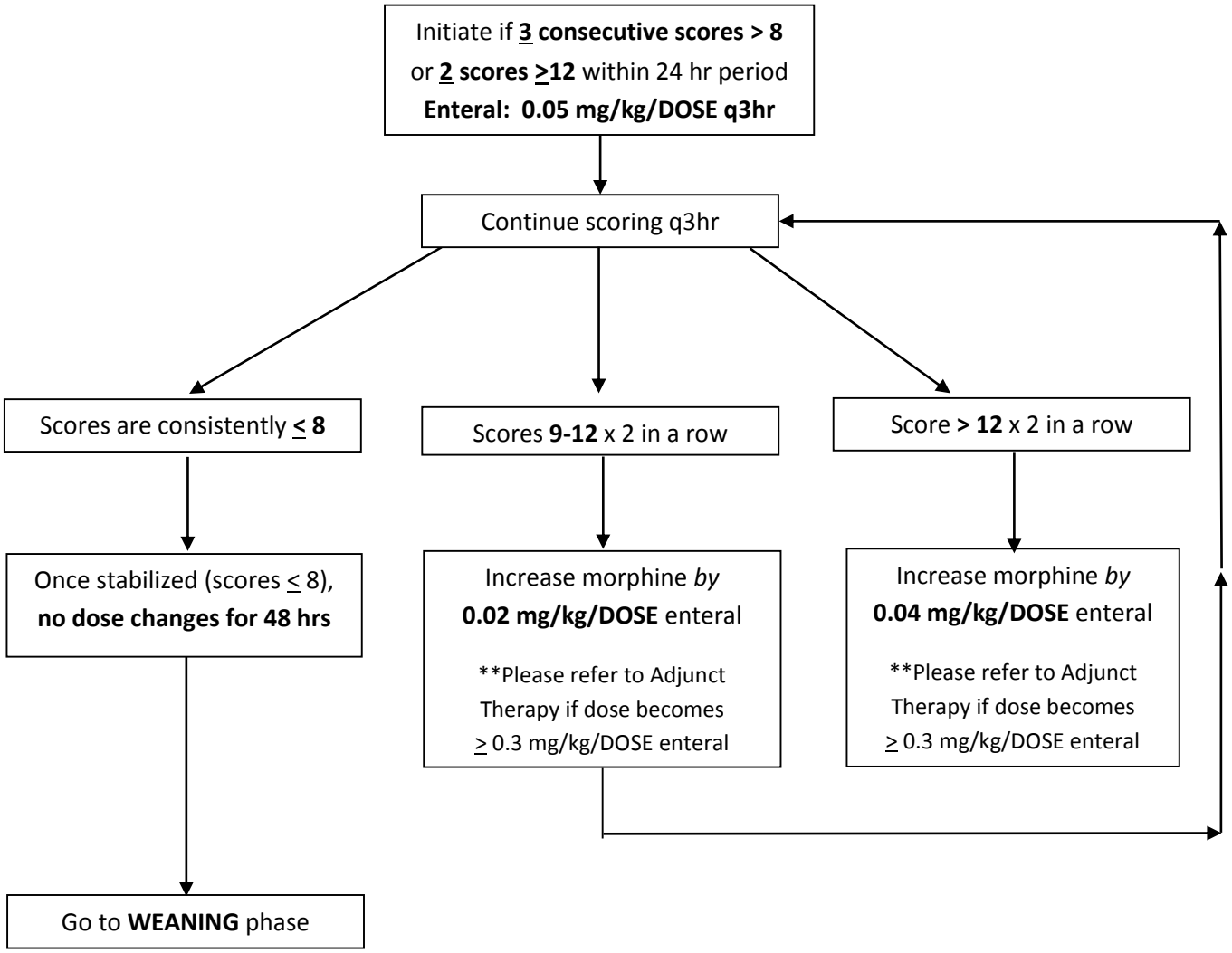
4e. NAS Morphine Discharge

- **Observe in-house x 48 hours off of morphine before discharge**

***The above protocol is for *enteral* dosing of Morphine. In the situation where an infant with NAS cannot have enteral morphine (ie gastrochisis, omphalocele, etc) IV morphine should be used. IV and enteral morphine doses are not equivalent. The IV initiation dose is 0.02mg/kg/dose every 3 hours. If the symptoms are not controlled, may increase the IV dose by 0.01mg/kg/dose every three hours until symptoms are controlled.**

Initiation, Escalation, Stabilization



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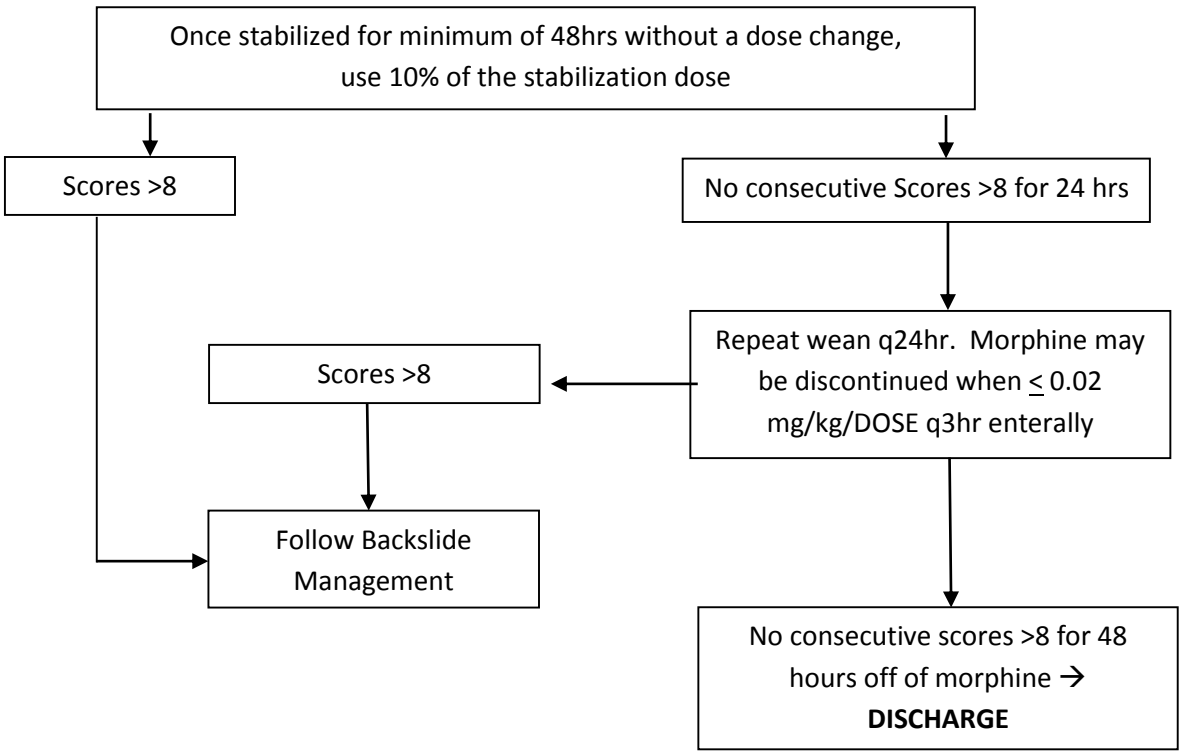
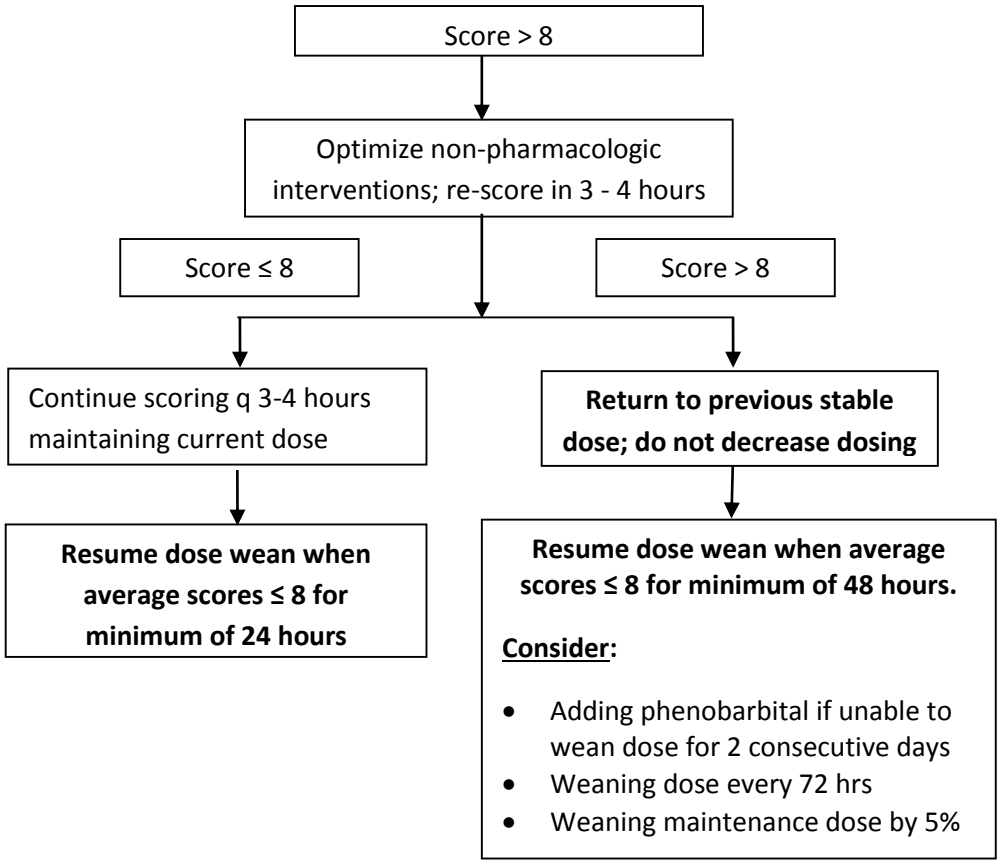
Weaning



Backslide Management for scores >8



The Ohio Perinatal Quality Collaborative

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